

**R E M A R K S**

The Applicants note that all amendments and cancellations of Claims are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),<sup>1</sup> and without waiving the right to prosecute the cancelled claims (or similar claims) in the future.

The Examiner has stated that the previously filed Invention Disclosure Statement of 05/10/2004 failed to comply with 37 CFR 1.98(a)(2) because the IDS does not include a legible copy of the Ford et al., Science 2001; 291:1051 reference (Office Action, pg. 3). The Applicants have attached a new copy of the Ford et al. reference to this communication and respectfully request that the reference be considered.

In the Final Office Action dated 10/31/06, the Examiner issued two rejections. Each of the rejections is discussed below.

**I. The Claims are Definite**

The Examiner rejects Claims 1 and 3-11 under 35 U.S.C. 112, second paragraph, as allegedly being incomplete for omitting essential steps (Office Action, pg. 3). The allegedly omitted steps are: a reference or control. The Applicants respectfully disagree. Nonetheless, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended Claim 1 to include additional language of an absence of antibodies to HIP1 being indicative of an absence of prostate cancer in the subject. As such, the Applicants believe that the rejection should be withdrawn.

**II. The Claims are Enabled**

The Examiner rejects Claims 1-11 under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement (Office Action, pg. 4). In particular, the Examiner states "Thus, the claims imply that the presence or absence of antibodies to HIP1 in any sample can be used to detect any/and or all cancers." (Office Action, pg. 4). The Applicants respectfully disagree. The

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<sup>1</sup> 65 Fed. Reg. 54603 (Sept., 8, 2000).


claims are clearly directed towards detection of **prostate** cancer: “wherein the presence of antibodies to HIP1 in said sample is indicative of prostate cancer in said subject” (Claim 1). Nonetheless, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended the preamble of Claim 1 to refer to a method for detecting prostate cancer. The Applicants have further amended Claim 1 to specify that the sample is a serum sample. As such, the Applicants submit that the Examiner’s statement that the claims are directed towards detecting any cancer in any sample is moot.

The Examiner further states: “In other words, 25% of the prostate cancer patient cohort was positive for a humoral response to HIP1, whereas 39% of the “normal” patient cohort were positive. In view of this teaching, it appears that the presence of antibodies to HIP, e.g., positive humoral response to HIP1, would be more indicative of a “normal” patient and not of a patient suffering from prostate cancer.” (Office Action, pg. 6). The Applicants respectfully disagree. The Applicants attach hereto a publication by the inventors utilizing a larger cohort of patients that demonstrates, per the teachings of the specification, a correlation between antibodies to HIP1 and prostate cancer (Bradley et al., Cancer Res. 65:4126 [2005]). In particular, Figure 3 (Western blot; pg. 4130) and Figure 4 (ELISA; pg. 4131) demonstrate that a higher percentage of prostate cancer patients relative to control individuals demonstrated a humoral response to HIP1. As such, the Applicants submit that the application is enabled for detection of a correlation between serum antibodies to HIP1 and prostate cancer. Accordingly, the Applicants submit that the claims are enabled and respectfully request that the rejection be withdrawn.

**CONCLUSION**

If a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call the undersigned collect at (618) 218-6900.

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